November 16, 2002

Dockets Management Branch
(HFA-305), Docket Number 02N-0466,
Food and Drug Administration,
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

Solicitation of Public Review and Comment on Research Protocol: A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax Administration to Children 2 to 5 Years of Age.

I am writing to you in regards to your testing of Dryvax on a 2-5 year old sample population. Is it ethical to test healthy children with a vaccine that has severe to fatal side effects that serve no purpose to them unless exposed to a bioterrorist attack with smallpox? The statistics are that for every million people vaccinated fifteen will suffer life-threatening illness and of that, one or two will die.

If the sample population takes the bandage off and touches the vaccinated site then touch their eye they will go blind. They are taken out of school for a month, who is going to teach them? Their social life will be interrupted and who is going to watch them because they will be isolated from everyone else.

The parents of the children have jobs and can't take care of them so they put the children in child daycare, but they have to be taken out of that as well. How are you going to pick the population only forty samples will be taken? Is it going to be diverse by race, sex, wealth status, and environment, is money involved for people who want to be part of this research? Only forty children are not enough to conclude a realistic project. That is such a small number that is like two classrooms and everyone is different so I don't agree with the study, it is pointless the way you are running it.

Sincerely,

Brent Kaloides